

SUBJECT: [REDACTED] Abbreviated Risk Assessment for J15-27 to -30

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***** [REDACTED] *****

I. INTRODUCTION

The Agency has received a Microbial Commercial Activity Notice from DSM Bio-based Products and Services (DSM Nutritional Products) for four intergeneric strains of

[REDACTED]



II. TAXONOMY AND CHARACTERIZATION

A. Recipient Microorganism



B. Donor Microorganisms

III. PRODUCTION VOLUME

The anticipated production volumes for the modified active dry yeast were given by quarters as follows:

IV. HISTORY OF USE

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

B. Potential Hazards of the Genetic Modifications

The potential hazards associated with the genetic modifications and the potential for horizontal gene transfer (hgt) have been reviewed by Tierney (2015).

1. Introduced Genes

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

2. Potential for Horizontal Gene Transfer

[REDACTED]

[REDACTED]

VI. HUMAN HEALTH HAZARDS

[REDACTED]

[REDACTED]

[REDACTED]

There is no concern for the use of antibiotic resistance genes since the five antibiotic selection markers used during construction of the submission microorganism were removed from the final constructs.

VII. ECOLOGICAL HAZARDS

[REDACTED]

[REDACTED]

[REDACTED]

The production strains may be expected to survive in the environment if inadvertently released from ethanol production facilities, however, their potential survival does not pose concerns.

VIII. INTEGRATED RISK ASSESSMENT

There is low risk to human health and the environment associated with the use of the four submission strains [REDACTED]

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